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(54) IMPROVEMENTS IN AND RELATING TO ELECTRICAL LEADS FOR CARDIAC PACEMAKERS

(71) I, EDWARD M. GOLDBERG, a citizen of the United States of America, of 26 Crescent Drive, Glencoe, Illinois, United States of America,

do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to means for electrically connecting a cardiac pacemaker to the heart of an animal or a human.

The beat of human and animal hearts is controlled by electrical impulses entering the atrium and passing through to the ventricles. When the travel of these electrical impulses from the atrium to the ventricles is partially or totally impeded this condition is referred to as a "heart block". For some time heart blocks have been corrected by attaching "cardiac pacemakers", small generators of electrical impulses, through electrical leads to the malfunctioning heart.

Cardiac pacemakers have been used to pace the heart in synchronous and non-synchronous manners. In synchronous pacing suitable equipment is connected to the atrium to pick up the beat of the atrium. This electrical beat is coordinated with electrical impulses sent by a cardiac pacemaker attached to the ventricles to achieve "synchronous" beating between the atrium and the ventricles.

In non-synchronous pacing the cardiac pacemaker is merely attached to the ventricle and the beating of the ventricles and atrium is not in complete harmony. The efficiency of the heart is reduced in non-synchronous pacing approximately 20%, but since it requires fewer attachments to the heart non-synchronous pacing has been the most commonly used pacing system.

Heretofore a thoractomy was commonly required to attach a cardiac pacemaker to the heart and the electrical leads were sutured into electrical contact with the heart. This technique has numerous disadvantages. Firstly, a thoracotomy, which requires a large incision in the chest or thorax, is drastic surgery and has a relatively high mortality rate. Secondly, suturing the electrical leads into electrical contact with the heart causes sever trauma to the heart, which it is desirable to minimise.

An intravenous connection has also been used to attach electrical leads of a cardiac pacemaker to the heart. In this technique the electrical lead is passed through a vein into the heart where it is held by fibrilla located in close proximity to the heart valve through which the lead is passed. There are, however, many disadvantages to this technique also, including: the possibility of damage to the vein during insertion, such as vein perforation; the failure to attach securely the electrical lead to the heart; and the possibility of perforating the heart wall with the electrical lead during insertion or after attachment has been completed.

According to one aspect of the present invention there is provided an electrical lead for a cardiac pacemaker which comprises an insulated electrically conductive section and a lead-in securing section including a helical member which may be screwed into the heart.

Preferably, the lead includes a non-insulated electrically conductive section between said insulated electrically conductive section and said lead-in securing section.

According to another aspect of the present invention there is provided an electrical lead for a cardiac pacemaker comprising an insulated electrically conductive section, a non-insulated electrically conductive section, and a lead-in securing section, said non-insulated electrically conductive section being between said other sections, the insulated electrically conductive section and the non-insulated electrically conductive section comprising a spring wire wound in a helix and provided with and without insulation respectively, said lead-in

securing section comprising an electrically conductive, substantially rigid wire wound in a helix and having a free end which terminates in a sharp point.

According to a further aspect of the present invention there is provided an electrical lead assembly for a cardiac pacemaker which comprises a first electrical lead and a second electrical lead, said first electrical lead comprising an insulated electrically conductive section and a lead-in securing section including a helical member which may be screwed into the heart, the second electrical lead comprising an insulated electrically conductive section and a non-insulated electrically conductive section, said second electrical lead being wrapped about the insulated conductive section of said first electrical lead.

In order that the present invention may be well understood there will now be described preferred embodiments therof, given by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a diagrammatic view of a cardiac pacemaker system attached to a human heart by electrical leads embodying the present invention;

Figure 2 is a partially cross-sectional enlarged fargmentary view of the muscle of a human heart with the electrical lead shown in Figure 1 attached thereto;

Figure 3 is a fragmentary, enlarged view of the electrical lead shown in Figure 1 with an insertion tool utilized to attach the electrical lead to the heart;

Figure 4 is a fragmentary, enlarged view of the electrical lead and insertion tool illustrated in Figure 3 showing another method of attaching the lead to the heart;

Figure 5 is a partially cross-sectional, enlarged view of a part of another embodiment of the present invention;

Figure 6 is an enlarged fragmentary view of a part of still another embodiment of the present invention; and

Figure 7 is a diagrammatic view of another cardiac pacemaker.

Referring now to Figure 1 there is illustrated diagrammatically a cardiac pacemaker 10 connected to a heart 12 of a human through electrical leads 14 and 16 to be described hereafter. Each of the electrical leads 14 and 16 has one end securely attached to the heart 12, and its opposite end attached to a single electrical plug 20, which is disconnectably attached to the cardiac pacemaker 10. In this instance the cardiac pacemaker 10 is connected to a muscle of the heart and, as is customary, is housed under the skin in the abdominal area. The cardiac pacemaker 10 must be replaced periodically *e.g.*, every 2—3 years. To do this an incision is made in the abdominal area adjacent the pacemaker 10, the plug 20 detached from the cardiac pacemaker 10 and attached to the new cardiac pacemaker and the incision closed.

The electrical leads 14 and 16 are identical. Referring to Figures 2, 3 and 4, each of these electrical leads comprises three sections; an insulated electrically conductive section 22, a non-insulated electrically conductive section 24, and a lead-in securing section 26. The insulated electrically conductive section 22 is preferably made of spring electrically conductive wire in this instance braided wire, coated with insulating material, which is wound in a helix. The electrically conductive wire may be made of any electrically conductive material which is non-toxic to the animal or human. The selection of a suitable electrically conductive material is a matter of choice within the ordinary skill of one skilled in the art. The insulating material may be any plastics or other insulating material which is non-toxic to the animal or human. The selection of a suitable insulating material is also a matter of choice within the ordinary skill of one skilled in the art. This spring helical wire will expand when tension is applied and return to its original length when the tension is released.

One end of the section 22 is attached by soldering or the like to the electrical plug 20 as illustrated in Figure 1. The other end is attached to, or in this instance forms, the non-insulated electrically conductive section 24. In this instance the section 24 is merely the same as the section 22 with the exception that the insulating material has been removed from the electrically conductive wire.

The lead-in securing section 26 is connected to the non-insulated electrically conductive section 24 and comprises a substantially rigid helical member, in this instance a helically wound wire, preferably having a sharp point 28 at its end. The shape and rigidity of the lead-in securing section 26 permit it to be attached to, and enhance its holding effect after attachment to, a muscle 30 of the heart 12 as illustrated in Figure 2. Preferably, the helix of the lead-in securing section 26 is tapered toward the point 28 as illustrated in Figures 2, 3 and 4. Alternatively, the helix of section 26 may be formed with a portion of the reduced diameter which will suffice for use with the insertion tool to be discussed hereinafter.

The lead-in securing section 26 may be made of any metal or plastics material which is non-toxic to the animal or human and connected by any means to the section 24. The selection of a suitable material and the means by which the sections are connected are matters of choice within the ordinary skill of one skilled in the art. Preferably, however, section 26 is made of an electrically conductive metal.

By way of example the insulated electrically conductive section 22 is generally about 8—12 inches in length and the helix of sec-

tion 22 has a diameter in the range of about 1/16" and 1/8". The helix of the non-insulated electrically conductive section 24 has, in this instance, the same diameter as the helix of section 22 and since the section 24 only comprises a few turns, as shown two turns, or less it will have a length generally less than 1/8". The helix of the lead-in securing section 26 preferably has its largest diameter equal to the diameter of the helices of the other sections and the section 26 is generally in the range of about 1/8" and 1/4" in length as a few turns, as shown three turns, are generally sufficient though fewer than three turns may be used.

Referring to Figure 3 the electrical lead 14 is attached or secured to the heart 12 with an insertion tool indicated generally by reference numeral 32. The insertion tool 32 has an elongated shaft 34 having a bevelled portion 36, like the end of a conventional screw driver, and a handle 38 at its respective ends. To prepare the electrical lead 14 for attachment to the heart, the bevelled end 36 of the insertion tool 32 is inserted betwn a turn in the helical wire of the conducting section 22, such as at point 40 illustrated in Figure 3, and pushed into the electrical lead 14 until the bevelled end 36 engages with and is gripped by the tapered portion of the lead-in securing section 26. By way of illustration, the insertion tool 32 is about 12 inches in length and the shaft 34 has a diameter of about .05 inches, which is less than the diameter of the helix of the insulated and non-insulated sections 22 and 24, respectively, of the electrical lead 14.

To prepare the heart for receiving the electrical lead, a small incision is made in the pericardium and epi-myocardial fascia (not shown) of the heart to expose the heart muscle 30 to which the electrical lead 14 is secured. The insertion tool 32, while engaging with and being gripped by the lead-in securing section 26, is rotated by hand to screw the lead-in securing section 26 into the heart muscle 30. As shown in Figure 2, the lead-in securing section 26 is rotated sufficiently so that this section, as well as the entire non-insulated electrically conductive section 24 and some turns of the insulated electrically conductive section 22, are screwed in the heart muscle 30. The insertion tool 32 is then withdrawn from the lead 14 and this lead is securely fastened to the heart 12. As the electrical lead 14 is being screwed into the heart muscle care should be taken to rotate the entire electrical lead 14, such as by rotating the terminal connector plug 20, otherwise there will be a tendency of the electrical lead 14 to unwind when the tool 32 is removed and thus unscrew from the heart muscle 30.

After the electrical lead 14 has been securely attached to the muscle 30 of the heart 12, the other electrical lead 16 is securely attached there to in a similar manner. There is, however, one significant variation. With the electrical lead 14 firmly implanted in the heart 12, one can no longer compensate for the tendency of the electrical lead 16 to wind up during insertion, and therefore unscrew when the hand tool 32 is released, by turning the plug 20 since that would cause the electrical lead 14 to be twisted and to tend undesirably to screw out of or further into the heart muscle 30. Therefore with the second electrical lead 16 the number of revlutions it will be screwed into the heart is predetermined and the electrical lead wrapped around the insertion tool 32, as illustrated in Figure 4, in the opposite direction the same number of turns. For example, if it will require eight clockwise rotations to to screw the electrical lead 16 into the heart muscle 30 the desired distance, then the electrical lead 16 is wrapped eight counterclockwise rotations around the insertion tool. In this manner the electrical lead 16, after attachment to the heart muscle 30, is not under any force caused by twisting of the wire which would tend to screw it out of or further into the heart muscle 30. As illustrated in Figure 4, the electrical lead 16 requires clockwise rotation for insertion and therefore it has been wrapped in a counterclockwise manner around the shaft 34 of the tool 32.

A significant feature of the above described electrical lead is that it may be secured to the heart through mediastinotomy, for example, which is a less drastic surgical procedure than a thoracotomy. However, it will be understood that the above described electrical lead may be utilized regardless of the surgical procedures employed to afford access to the heart.

Another important feature of the electrical lead is that it causes less trauma to the heart than heretofore known electrical leads. In addition to the general desirability of minimizing trauma to the heart for the well being of the patient, heart trauma plays an important part in a heart pacing system. In the areas where the heart has been subjected to trauma scar tissue forms. Scar tissues do not conduct electricity. Therefore, the greater the area of scar tissue, the more current needed for the electric impulses to reach the receptive tissue of the heart. Increased current requires larger batteries or electricity generators and thus the size of the pacemaker is increased. The larger the pacemaker the more inconvenient it is for the body to carry it and the less chance of concealing it in the abdominal area of a human.

The heart is continually in motion by virtue of its constant expansion and contraction, which places great stress upon the juncture between the substantially rigid lead-in securing section 26 and the section 24. If there should be any breakage it is most likely to occur at this juncture. Should this occur the exposed turns in section 24 assure that electricity will

continue to be provided to the heart muscle 30. It is anticipated of course, that the electrical leads 14 and 16 are screwed into the heart muscle 30 sufficiently so that there are least few turns of the section 22 in the heart muscle 30 also. The more turns that are embedded in the heart muscle, the stronger the attachment of the electrical lead to the heart.

It is preferred that the electrical leads 14 and 16 be screwed into the heart muscle so that they are positioned substantially tangential to the heart muscle and tend to run parallel with it, as illustrated in Figure 2, rather than perpendicular thereto. It has been found that this substantially reduces the chances of the section 26 breaking off from the rest of the electrical lead.

Figure 5 illustrates another embodiment of an electrical lead according to the present invention which is indicated generally by reference numeral 50. The electrical lead 50 has an insulated electrically conductive section 22 and a non-insulated electrically conductive section 24 as have the electrical leads 14 and 16. However, the lead-in securing section 52 comprises a hollow, tapered or conical member which may be electrically conductive and has a helical ridge 54 on its outer periphery which terminates at a sharp leading point 56. This electrical lead 50 is attached to the heart in the same manner as the leads 14 and 16 discussed hereinbefore and has all of the advantages of these leads also. However, it has the further advantage that it is unnecessary to cut the epi-myocardial fascia, as required when using the electrical leads 14 and 16 because of bunching or curling of the fascia during insertion.

Although it is preferred that the insulated and non-insulated electrically conductive sections 22 and 24, respectively, be made of spring helical wire, it will be understood that any other type of wire may alternatively be used if sufficient slack is left to allow for the movement of the heart. Furthermore, though it is prefered to include the section 24, it will be understood that it may be omitted so long as the section 26 is made of electrically conductive material.

Figure 6 illustrates an embodiment of an electrical lead assembly according to the present invention and which is indicated generally by reference numeral 60. This lead assembly comprises two electrical leads 62 and 64. The electrical lead 62, as illustrated, is the same as in construction as the electrical leads 14 and 16 discussed hereinbefore, but it is to be understood that it may alternatively be the same in construction as the electrical lead 50. The electrical lead 64 is the same as one of the leads 14, 16 and 50 without the lead-in securing section and is wound in the helical spaces of the electrical lead 62. The non-insulated conductive section 66 of the lead 64 begins and terminates within the length of the non-insulated section 68 of the electrical lead 62 to prevent a short circuit between the leads. The electrical lead 60 is installed in the same manner as the electrical leads 14, 16 and 50 and inserted sufficiently so that the non-insulated conductive section 66 of the lead 64 is within the heart muscle. If the insulated and non-insulated electrically conductive sections of the leads 62 and 64 are not made of spring helical wire as illustrated in Figure 6, the lead 64 is twisted or wrapped about the lead 62, the non-insulated section of the lead 64 terminating adjacent to, but spaced from, the non-insulated section of the lead 62. Minimization of trauma to the heart and the elimination of the problem discussed in connection with Figure 4 are some of the features afforded by this embodiment.

Figure 7 illustrates another cardiac pacemaker system employing loads as described with reference to Figures 2 to 5. In this instance each electrical lead 70 is connected to its own electrical terminal connector plug 72 and may be separately connected and disconnected to the cardiac pacemaker 74. This eliminates the special procedures discussed in connection with Figure 4 and permits each electrical lead 70 to be installed in the same manner as electrical lead 14 discussed hereinbefore.

It has further been discovered that in the type of electrical leads discussed herein there is generally a small space between the electrical conducting wire and the insulating material which creates a capillary action after the electrical lead has been attached to the heart and undesirably draws blood from the heart muscle into the insulating material. It has been found that this may be obviated by coating the ends of the insulated sections of the electrical leads with a suitable liquid sealing material, such as epoxy resin or the like. The capillary action will draw the liquid sealing material into the space between the insulating material and the electrical wire to seal off the space upon hardening of the sealing material.

Where the human heart block is a S-A node blockage, the condition may be corrected by attaching the leads of the cardiac pacemaker directly to the atrium. Any of the leads and procedures discussed hereinbefore may be used.

The lack of blood vessels around the human heart is referred to as ischemia and causes coronary insufficiency. The build-up of blood vessels around the heart may be effected by attaching a cardiac pacemaker by any of the methods discussed hereinbefore directly to the atrium. In this manner the heart may be paced at a faster rate than it normally operates and will effect continual mild exercise of the heart. The development of more blood vessels about the heart muscle resists coronary insufficiency and lessens the likelihood of a heart attack.

While the embodiments described herein

are at present considered to be preferred, it will be understood that various modifications and improvements may be made therein within the scope of the invention as defined by the appendant claims.

WHAT I CLAIM IS:—

1. An electrical lead for a cardiac pacemaker which comprises an insulated electrically conductive section and a lead-in securing section including a helical member which may be screwed into the heart.

2. An electrical lead according to Claim 1 including a non-insulated electrically conductive section between said insulated electrically conductive section and said lead-in securing section.

3. An electrical lead according to Claim 2 wherein said insulated and non-insulated electrically conductive sections comprise a spring wire wound in a helix and provided with insulation and without insulation respectively.

4. An electrical lead according to any of the preceding Claims wherein said helical member is a substantially rigid wire wound in a helix.

5. An electrical lead according to Claim 4 wherein said rigid wire is electrically conductive.

6. An electrical lead according to either Claim 4 or Claim 5 wherein the helix of said rigid wire has a portion of reduced diameter.

7. An electrical lead according to either Claim 4 or Claim 5 wherein said rigid wire has a free end and the helix of said rigid wire is tapered in diameter toward said free end.

8. An electrical lead according to any of Claims 1 to 3 wherein said helical member is a hollow member having a helical thread about its periphery.

9. An electrical lead according to Claim 8 wherein said helical member has a free end and is tapered in diameter toward its free end.

10. An electrical lead according to either Claim 8 or Claim 9 wherein said hollow member is electrically conductive.

11. An electrical lead for a cardiac pacemaker comprising an insulated electrically conductive section, and a lead-in securing section ductive section, a non-insulated electrically consaid non-insulated electrically conductive section being between said other sections, the insulated electrically conductive section and the non-insulated electrically conductive section comprising a spring wire wound in a helix and provided with and without insualtion respectively, said lead-in securing section comprising an electrically conductive, substantially rigid wire wound in a helix and having a free end which terminates in a sharp point.

12. An electrical lead according to any of the preceding Claims including terminal connector means for attaching it to a cardiac pacemaker.

13. An electrical lead assembly for a cardiac pacemaker which comprises a first electrical lead and a second electrical lead, said first electrical lead comprising an insulated electrically conductive section and a lead-in securing section including a helical member which may be screwed into the heart, the second electrical lead comprising an insulated electrically conductive section and a non-insulated electrically conductive section, said second electrical lead being wrapped about the insulated conductive section of said first electrical lead.

14. An electrical lead assembly according to Claim 13 wherein said first electrical lead includes a non-insulated electrically conductive section between the insulated electrically conductive section and the lead-in securing section.

15. An electrical lead assembly according to claim 14 wherein said insulated and non-insulated electrically conductive sections of each lead are made of spring wire wound in a helix and provided with and without insulation respectively, said second electrical lead being wound in the helical spaces of the helically wound insulated electrically conductive section of said first electrical lead and having its non-insulated section adjacent to but spaced from the non-insulated section of said first electrical lead.

16. An electrical lead assembly according to any of claims 13 to 15 wherein said helical member is a substantially rigid, electrically conductive wire wound in a helix and having a free end with a sharp point.

17. An electrical lead for a cardiac pacemaker, substantially as herein described with reference to the accompanying drawings.

18. An electrical lead assembly substantially as herein described with reference to the accompanying drawings.

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1277107 COMPLETE SPECIFICATION

1 SHEET *This drawing is a reproduction of the Original on a reduced scale*